K120135

APR 13 2012

TOMTEC
IMAGING SYSTEMS

April 11th, 2012

Traditional 510(k) Summary

2D Cardiac Performance Analysis MR 1.0

Owner's Name and Address
TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person
Inge Scheidt
QM & RA Officer
Phone ++49-89-32175-515
Fax ++49-89-32175-750

Common, Classification & Proprietary Names
Common Name: Various Image Analysis System Software
Classification Name: Picture Archiving and Communications System
Proprietary Name(s): **2D Cardiac Performance Analysis MR 1.0**

Predicate Devices

Predicate Device 1	K090461	Image-Arena 4.0 and Image-Arena Applications 2D Cardiac Performance Analysis, TomTec 2D Cardiac Performance Analysis component, only
Predicate Device 2	K100352	Diagnosoft HARP 2.06, Diagnosoft, Inc.

The Subject Device "2D Cardiac Performance Analysis MR 1.0" is an adapted version of the Predicate Device 1 (K090461) 2D Cardiac Performance Analysis 1.0. It is adapted to the use with magnetic resonance images (MRI).

A central component of the Subject Device is the tracking which is also provided in Predicate Device 2 (K100352) Diagnosoft HARP 2.06 based on magnetic resonance images.

TOMTEC IMAGING SYSTEMS

Device Description

2D Cardiac Performance Analysis MR (=2D CPA MR) is a clinical application package for high performance PC platforms based on Microsoft® Windows® operating system standards. 2D CPA MR is a software for the analysis, storage and retrieval of digitized magnetic resonance (MR) images.
The data can be acquired by cardiac MR machines. The digital 2D data can be used for comprehensive functional assessment of the myocardial function.

2D CPA MR is designed to run with a TomTec Data Management Platform (Image-Arena™, their derivatives or any other platform that provides and supports the Generic CAP Interface. The Generic CAP Interface is used to connect clinical application packages (=CAPs) to platforms to exchange digital medical data.
The TomTec Data Management Platform enhances the workflow by providing the database, import, export and other advanced high-level research functionalities.

2D CPA MR is designed for the 2-dimensional functional analysis of myocardial deformation. Based on two dimensional datasets a feature tracking algorithm supports the calculation of a 2D contour model that represents the endocardial and epicardial border. From these contours the corresponding velocities, displacement and strain can be derived.

Intended Use

2D CPA MR software is intended for quantification of the myocardial deformation (strain) and movement (displacement / velocity) for digital magnetic resonance images. Possible quantification results are velocity, displacement, strain, strain rate, time-to-peak and phase.
Prerequisite is to draw a contour (endocard or endocard and epicard) in a digital magnetic resonance image. Based on this manual drawn contour, the SW calculates with a tracking algorithm the borders' displacement.

Indication for Use

2D Cardiac Performance Analysis is intended for cardiac quantification based on magnetic resonance images. It provides measurements of myocardial function (displacement, velocity, strain, strain rate) that is used for diagnostic purposes of patients with suspected heart disease.

Technological Characteristics Comparison

The actual submission combines the advantages of the FDA cleared software products:

Predicate Device 1	K090461	Image-Arena 4.0 and Image-Arena Applications 2D Cardiac Performance Analysis, TomTec 2D Cardiac Performance Analysis component, only

TOMTEC IMAGING SYSTEMS

Predicate Device 2	K100352	Diagnosoft HARP 2.06, Diagnosoft, Inc.

The Subject Device provides measurements to analyze the myocardial function on cardiac magnetic resonance images like Predicate Device 1 (K090461) and Predicate Device 2 (K100352).

The tracking technology of the Subject Device is sensitive enough to track the grey value patterns of regular MRI, thus eliminating the need of additional acquisition of tagged images, which are usually the basis for Predicate Device 2 (K100352). The tracking of the Subject Device delivers contours of different regions of the myocardium like in Predicate Device 1 (K090461) and Predicate Device 2 (K100352).
Based on the tracking results regional measurements like strain can be derived like in Predicate Device 1 (K090461) and Predicate Device 2 (K100352).
The parameters can be expressed in their spatial directions (e.g. circumferential, radial) like in Predicate Device 1 (K090461) and Predicate Device 2 (K1003526).
An overlay of the tracked contours as well as graph displays for the measured parameters are available like in Predicate Device 1 (K090461) and Predicate Device 2 (K100352).
The Subject Device is connected to the data management platform via the Generic Clinical Application Package Interface like Predicate Device 1 (K090461).

Discussion according non-clinical performance data testing

Testing was performed according to internal company procedures.
Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted.

The test procedure was performed according to the Project Quality Plan.
Test results were reviewed by designated technical professionals before software proceeded to release.

The results are summarized in the test summary report.
The conclusion states that:

- Verification strategies and test procedures used are appropriate
- Software system test procedures trace to software requirements
- All software requirements are tested or otherwise verified
- Test results meet the required pass/fail criteria

Discussion according clinical performance data testing

The overall product concept was clinically accepted and the clinical test results support the conclusion that the Subject Device is as safe as effective, and performs as well as the Predicate Devices.

A clinical evaluation following the literature route based on the assessment of benefits, associated with the use of the device, was performed. The clinical evaluation shows that the published data are relevant and applicable to the relevant characteristics of the device under assessment and the medical procedure for which the device is intended.

Risk analysis aspects were treated in the risk management report. Based on this document the existing applied methods in the literature and the newly described techniques of the product (which are considered in the risk analysis) were evaluated.

No further risks were identified.

Conclusion from the analysis of the literature review

- The Risk-Benefit Assessment shows that the benefit is superior to the risk (whereas the risk is low).
- The 2D feature tracking method based on 2D MR image data is already published. The use is as accurate as standard procedures such as HARP (for MR) or 2D speckle tracking (for echo) and it is feasible for clinical practice.
- The quantitative results have been discussed controversial with existing methods.
- The approach of drawing manual contour on standard MR images combined with a 2D feature tracking doesn't change the clinical intention of the product. The workflow reduces time in contrast to dedicated MRI examination such as tagged imaging or late enhancement imaging.
- The data are sufficient to demonstrate compliance with the essential requirements covering safety and performance of the device in question under normal conditions of use.
- The claims made in the device labelling are substantiated by the clinical data.

Test Conclusions of non-clinical and clinical performance data

Test results support the conclusion, that the Subject Device is as safe as effective, and performs as well as or better than the Predicate Devices.

No reportable events or problems for the Predicate Devices exist.
The overall product concept was clinically accepted and the test results support the conclusion that the Subject Device is as safe as effective and performs as well as the Predicate Devices.

Munich, April 11th, 2012

Inge Scheidt
QM & RA Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

APR 13 2012

Ms. Inge Scheidt
QM & RA Officer
TomTec Imaging Systems GmbH
Edisonstrasse 6, Unterschleissheim
Bavaria D-85716
GERMANY

Re: K120135
Trade/Device Name: 2D Cardiac Performance Analysis MR 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 13, 2012
Received: January 17, 2012

Dear Ms. Scheidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120135

Device Name:

2D Cardiac Performance Analysis MR 1.0

Indications for Use:

The clinical application package 2D Cardiac Performance Analysis MR is indicated for cardiac quantification based on digital magnetic resonance images. It provides measurements of myocardial function (displacement, velocity and strain) that is used for clinical diagnosis purposes of patients with suspected heart disease.

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120135

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)